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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/302,024	04/29/1999	JOHN EDWARD HODGSON	P31353-	6373

25308 7590 10/15/2003

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EXAMINER

KERR, KATHLEEN M

ART UNIT PAPER NUMBER

1652

DATE MAILED: 10/15/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/302,024	Applicant(s) HODGSON ET AL.	
	Examiner Kathleen M Kerr	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 August 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 28-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 30-35 is/are allowed.
- 6) ☒ Claim(s) 28, 29 and 36-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 08/785,455.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Application Status

1. The instant application has been previously suspended (Paper No. 14) due to a potential *ex parte* interference. This issue has been resolved and prosecution is being reopened herein. Claims 28-47, previously noted as being allowed, are pending in the instant Office action and will be examined herein in full consideration of present Office policies and practices.

Priority

2. The instant application is granted the benefit of U.S. non-provisional application 09/785,455 filed on January 17, 1997. The instant application is also granted the benefit of priority for the foreign applications 9601095.4 and 9615845.6 filed in the United Kingdom on January 19, 1996 and July 27, 1996, respectively, as requested in the declaration. The Examiner notes that the full-length methionyl tRNA synthetase sequence is disclosed in the latter foreign application; thus, the pending claims are afforded an earliest effective filing date of July 27, 1996.

Information Disclosure Statement

3. The information disclosure statement filed on April 29, 1999 has been previously considered as noted in Paper No. 12.

Objections to the Specification

4. The specification is objected to for having inconsistent citations. Throughout most of the specification, reference material is noted in parentheses immediately following the passage.

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However, on pages 29-30, superscripts are introduced with a reference section on page 30.

Consistency in citation of references is required.

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 28, 29, and 36-47 are rejected under 35 U.S.C. § 112, first paragraph, written description, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The polypeptides of Claims 28-29 are not limited by a specific function since ability to induce antibodies is not the catalytic function as disclosed. The polypeptides of Claims 36-47 are not limited by a *specific* structure and function since the function lacks the specificity disclosed in the specification – SEQ ID NO:2 is a methionyl tRNA synthetase. Moreover, the polypeptides do not require a structure that would be expected to have a specific function since 30 amino acids of SEQ ID NO:2 would not be expected to have methionyl tRNA synthetase functionality.

The Court of Appeals for the Federal Circuit has recently held that a “written description of an invention involving a chemical genus, like a description of a chemical species, ‘requires a precise definition, such as be structure, formula [or] chemical name,’ of the claimed subject matter sufficient to distinguish it from other materials.” *University of California v. Eli Lilly and Co.*, 1997 U.S. App. LEXIS 18221, at *23, quoting *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed.

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Cir. 1993) (bracketed material in original). To fully describe a genus of genetic material, which is a chemical compound, applicants must (1) fully describe at least one species of the claimed genus sufficient to represent said genus whereby a skilled artisan, in view of the prior art, could predict the structure of other species encompassed by the claimed genus and (2) identify the common characteristics of the claimed molecules, e.g., structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these.

The instant specification teaches a polynucleotide (SEQ ID NO:1) encoding a methionyl tRNA synthetase (tRS) from *S. aureus* (SEQ ID NO:2). Applicants have fully described the genus relating to said SEQ ID NOs with both sequence identity limitations (a limited number of mutations) and functional limitations (i.e., having methionyl tRS activity). However, the genus of the instant claims also contains polypeptides within the sequence identity limitations, but having different function. Applicants have not fully described a genus that has sequence identity limitations in the absence of specific, functional limitations. The requirement of methionyl tRS is evident because the specification does not teach other tRSs of any sequence.

Moreover, with respect to the open, fragment language in Claims 36-47, the specification does not adequately support the claimed scope. Polypeptides having only 30 or 50 residues of SEQ ID NO:2 and having methionyl tRS activity are not adequately described by the single species of full-length SEQ ID NO:2 because one of skill in the art would be unable to predict the remaining structure (outside the 30 or 50-mer fragment) that would support the claimed function. Thus, the open, fragment language, even if specific functional language is amended into the claims, is not adequately supported by the specification.

For Claims 28-29, the Examiner suggests requiring the specific activity of having methionyl tRNA synthetase for the claimed polypeptide. Moreover, for polypeptide fragments of SEQ ID NO:2 in Claims 36-47, the Examiner suggests closed (consisting of) language.

6. Claims 28, 29 and 36-47 are rejected under 35 U.S.C. § 112, first paragraph, scope of enablement, because the specification, while being enabling for SEQ ID NO:2 polypeptides having methionyl tRNA synthetase activity, does not reasonably provide enablement for polypeptides having as few as 30 residues in common with SEQ ID NO:2 and having methionyl tRNA synthetase activity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. To make a significant portion of all the embodiments encompassed by the claims would require undue experimentation.

The factors to be considered in determining whether undue experimentation is required are summarized in *re Wands* 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir, 1988). The Court in *Wands* states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.'" (*Wands*, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (*Wands*, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or

absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. While all of these factors are considered, a sufficient amount for a *prima facie* case is discussed below.

The instant specification teaches SEQ ID NO:2, a methionyl tRNA synthetase (tRS) protein from *S. aureus*, and SEQ ID NO:1, an *S. aureus* gene exactly encoding SEQ ID NO:2. The art includes few examples of methionyl tRS encoding genes. The art fully enables any DNA encoding SEQ ID NO:2 based on the degeneracy of the genetic code. While the instant specification describes and enables means for identifying other methionyl tRS genes using hybridization methods, etc., these methods do not enable one of skill in the art to make all, or a relevant portion of, the polynucleotides within the scope of the claims because the ability to find a methionyl tRS gene, which is structurally related to SEQ ID NO:1, is not equivalent to the ability to make a methionyl tRS gene as required by the statute (i.e., "make and use"). No description in the specification or the art provides particular residues whose encoding is important within the disclosed sequence so that its methionyl tRS -nature is maintained. Thus, one of skill in the art would be unable to predict the structure of the other members of the genus in order to make such members. Therefore, the instant claims are not enabled to the full extent of their scope.

Summary of Pending Issues

7. The following is a summary of the issues pending in the instant application:
- a) The specification stands objected to for having inconsistent citations.
 - b) Claims 28, 29, and 36-47 stand rejected under 35 U.S.C. § 112, first paragraph, written description.
 - c) Claims 28, 29 and 36-47 stand rejected under 35 U.S.C. § 112, first paragraph, scope of enablement.

Examiner's Comments

8. The Examiner notes that SEQ ID NO:1 exactly encodes SEQ ID NO:2, starts with an "atg" and ends with a stop codon. The specification teaches methionyl tRNA synthetase activity of "purified MRS overexpressed in *E. coli*"; no direct mention of overexpression of SEQ ID NO:2 using a vector containing SEQ ID NO:1 in *E. coli* is found. However, SEQ ID NO:2 seems to be a full-length protein, and the Examiner has no reason to disagree with its assignment as a methionyl tRS.

Conclusion

9. Claims 30-35 are allowed. Claims 28, 29 and 36-47 are rejected for the reasons identified in the numbered sections of this Office action. Applicants must respond to the objections/rejections in each of the numbered sections in this Office action to be fully responsive in prosecution.

The instant Office action is **NON-FINAL** based on the new grounds of rejection presented in the instant Office action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (703) 305-1229.

The examiner can normally be reached on Monday through Friday, from 8:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (703) 308-3804. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

KMK

October 13, 2003

